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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,972	07/11/2000	P. Mickey Williams	P1765R1	1529

7590 07/09/2004

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,972	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 1-3 and 13-16 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 4-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/1/01+2/14/01.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of applicant's election of Group III, drawn to methods of treating cardiovascular, endothelial or angiogenic disorders in a mammal comprising administering a PRO364 or a PRO175 polypeptide and applicant's election of the species of PRO175 polypeptide. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP ' 818.03(a)).

Claims 1-16 are pending. Claims 1-3 and 13-16, drawn to non-elected inventions, are withdrawn from consideration. Claims 4-12 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 10 and 12 recite "cardiovascular, endothelial and angiogenic" rather than "cardiovascular, endothelial or angiogenic" in the alternative. This would require the treated disorder to have all the characteristics of a cardiovascular, endothelial and angiogenic disorder. Dependent claim 5 recites the disorders of cardiac hypertrophy, trauma or cancer. Dependent claim 12 recites the disorder of cancer. It appears that claims 8, 10 and 12 encompass cardiovascular, endothelial or angiogenic disorders, rather than disorder characterized by all three of the aforesaid limitations, because trauma and cancer need not encompass a cardiovascular disorder. For purpose of examination, claims 8, 10 and 12 will be read as --- cardiovascular, endothelial or angiogenic---.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 4 is drawn in part to a method of treating a cardiovascular, endothelial or angiogenic disorder in a mammal comprising administering an effective amount of the PRO175 polypeptide. Claim 5 embodies the method of claim 4 wherein the cardiovascular, endothelial or angiogenic disorder is cardiac hypertrophy, trauma or cancer. Claim 6 embodies the method of claim 4 wherein said mammal is human. Claim 7 embodies the method of claim 5 wherein said cardiac hypertrophy is characterized by the presence of an elevated level of prostaglandin F- 2 alpha. Claim 8 embodies the method of claim 5 wherein said cardiac hypertrophy has been induced by myocardial infarction. Claim 9 embodies the method of claim 8 wherein the administration of the PRO175 polypeptide is initiated within 8 hours of myocardial infarction. Claim 10 embodies the method of claim 4 wherein the cardiovascular disorder is cardiac hypertrophy and the PRO175 polypeptide is administered together with a cardiovascular, endothelial or angiogenic agent. Claim 11 embodies the method of claim 10 wherein said cardiovascular, endothelial or angiogenic disorder is selected from the group consisting of an hypertensive drug, an ACE-inhibitor, and endothelin receptor antagonist and a thrombolytic agent. Claim 12 embodies the method of claim 4 wherein the cardiovascular, endothelial or angiogenic disorder is cancer and the PRO175 polypeptide is administered in combination with a chemotherapeutic agent, a growth inhibitory agent or a cytotoxic agent.

The instant claims are drawn to methods reliant upon the identity of the PRO175 polypeptide. The specification states on page 22-23 that the PRO175 polypeptide refers to SEQ ID NO:14, naturally-occurring truncated or secreted forms of a PRO175 polypeptide, including as an example a soluble extracellular domain, naturally occurring variant forms, alternatively-

spliced form and naturally occurring allelic variants. The instant specification has provided no teachings regarding the activation of the AITR receptor which would result in the inhibition of cardiomyocyte hypertrophy. On page 23, lines 1-2, the specification states that an embodiment of the invention is a PRO175 polypeptide comprising residues 52-177 of SEQ ID NO:14. the specification also includes deletions variants or fragments of the full length polypeptide and that "preferably, such deletions variants or fragment possess a desired activity, such as described herein". this recitation of a preferred embodiment does not impart a required functional attribute onto PRO175 polypeptides within the context of the claims. The specification states on page 23 that a variant PRO175 polypeptide includes polypeptides having at least 80% sequence identity with SEQ ID NO:14., but does not limit the variants in terms of functional attributes. By the definitions provided in the specification, it can be concluded that the PRO175 polypeptide encompasses a genus of polypeptide. This genus is highly variant because it tolerates molecules which deviated significantly from SEQ ID NO:14 and have functional attributes which differ from SEQ ID NI:14.

(A) Alternatively-spliced and naturally occurring allelic and truncated variants.

The specification contemplates PRO175 polypeptides as encompassing allelic variants. The specification does not provide any particular definition of an allele, thus the meaning of the term is taken to be the ordinary usage in the art. The ordinary meaning of the term allele embraces alternate forms of a protein which differs from other proteins encoded by other alleles at one or more amino acid residues. The specification does not limit allelic proteins as those proteins which have the same phenotype as that of SEQ ID NO:14. Although the standard definition refers to genomic sequence and the claims are directed to polypeptide, a reasonable interpretation is that the claims are directed to proteins encoded by genomic sequence that include naturally occurring mutational sites. The specification discloses only one allele within the scope of the genus: SEQ ID NO:14. The specification proposes to discover other members of the genus by using a hybridization procedure. there is no description of other allelic proteins that exist in nature, and there is no description of how any structure of an allelic polypeptide is representative of unknown allelic polypeptides. the nature of alleles is that they are variant structures and in the present state of the art, the structure of one naturally occurring allelic polypeptide does not provide guidance to the structure of other naturally occurring allelic

polypeptides. The common attributes of the genus are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representation of the variants of the genus and is insufficient to support the claim.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the PRO175 per Lilly by structurally describing a representative number of PRO175 polypeptides or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the genus of PRO175 polypeptides in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide examples of a PRO175 polypeptide variant, nor does the specification provide any partial structure of such PRO175 polypeptide nor limit the PRO175 polypeptide to those having a specific physical or chemical characteristics. Although the specification discloses a single PRO175 polypeptide as SEQ ID NO:14 and a preferred embodiment comprising residues 52-177 of SEQ ID NO:14, this does not provide a description of the broad genus of truncated, deleted, allelic variant, alternative-spliced, or 80% variants that would satisfy the standard set out in Enzo.

The specification also fails to describe the genus of PRO175 polypeptide on which the instant method claims rely by the test set out in Lilly. The specification describes only a single PRO175 polypeptide of SEQ ID NOL14 and a single fragment of residues 52-177. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the PRO175 polypeptide relied upon in the instant method claims. Since the specification fails to adequately describe the product on which the claimed methods rely, it also fails to adequately describe the claimed methods.

Claims 4-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating the angiogenic disease of cancer comprising the administration of the PRO175 polypeptide, does not reasonably provide enablement for methods of treating cardiovascular hypertrophy or trauma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The instant methods claims are drawn in part to a method of treating cardiovascular and endothelial disorders in a mammal. The prior art identifies the PRO175 polypeptide of SEQ ID NO:14 as the TL6 ligand which binds to the AITR receptor (Kwon et al, Journal of Biological Chemistry, 1999, Vol. 274, pp. 6056-6061, reference 3 of the IDS filed March 1, 2001, abstract and page 6060, figure 4A) which is a human homologue of the GITR receptor. The AITR receptor is a member of the tumor necrosis family receptor superfamily (Kwon et al, abstract) and is expressed in lymph nodes, peripheral blood leukocytes and peripheral mononuclear cells after CD28 activation (abstract), and the TL6 ligand was found to be expressed in endothelial cells. TNF and TNF homologues are known to contribute to tissue damage during cardiovascular and endothelial disorders and the art teaches method of treating vascular diseases comprising the administration of TNF antagonists, rather then TNF ligands (Elliot et al, WO 97/30088, abstract, the abstract of Matsumori et al, European Heart Journal, 1995, Vol. 16, pp. 140-143, the abstract of Wakefield, Arteriosclerosis, Thrombosis and Vascular Biology, 1995,

Vol. 15, pp. 258-268, the abstract of Willette et al, Stroke, 1997, Vol. 28, pp. 1233-1244). The prior art teaches that the murine homolog of AITR, GITR, inhibits T-cell receptor-induced apoptosis (Kwon et al, page 6056, second column, lines 10-12) and that the binding of TL6 to AITR results in activation of Nf-kB (page 6060, first column, lines 41-44) and suggests that AITR and the TL-6 ligand is important for activated T-cell trafficking (page 6060, second column, last sentence). The art teaches the full length polypeptide of SEQ ID NO:14 as being encoded by the DNA19355 polypeptide, said polypeptide stimulating secretion of TNF-alpha in primary T-cells in vitro (Ashkenazi et al (US 200200146389, paragraph [0062]). The art teaches that hypertrophy of cardiac ventricular myocytes is a response to chronic homodynamic overload and that this response is characterized by an increase in the size of myocytes rather than increase in the number of myocytes (Jin et al, US 6,187,304, column 3, lines 12-22). The instant specification has provided no teachings regarding the activation of the AITR receptor which would result in the inhibition of cardiomyocyte hypertrophy, and it would be expected in light of the prior art which teaches the ablation of TNF as a treatment of vascular diseases, that the administration of a TNF homolog would not be beneficial to a mammal suffering from hypertropic cardiomyopathy. Further, in light of the teachings of Kwon et al, it would appears that endothelial expression of TL6 would recruit T-lymphoyctes to areas of the endothelium expressing TL-6, such as areas of high endothelial venues. The instant specification does not teach how the recruitment of activated T-cells to areas of high endothelial venues would prevent or reduce cardiomyocyte hypertrophy. Further, the instant specification teaches that the PRO175 polypeptide encompasses truncation mutants, deletion mutants, allelic variants and 80% variants but does not teach how alterations in structure affect the binding to the AIT receptor or any other TNF receptor. Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, as disclosed by Burgess et al (Journal of Cell Biology, 1990, Vol. 111, pp. 2129-2138), replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein.. As another example, replacement of aspartic acid at position 47 with alanine or asparagine in transforming growth factor alpha did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. (Lazar et al, 1988, Molecular and Cellular Biology Vol. 8, pp. 1247-

1252). These references demonstrate that even a single amino acid substitution or what appears to be a minor chemical modification will often dramatically affect the biological activity and characteristic of a protein. Clearly, it could not be predicted that a protein variant having 80% sequence identity with SEQ ID NO:14 will function as suggested. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use variants of SEQ ID NO:14 in methods of treating cardiovascular hypertrophy or trauma or angiogenic diseases. Given the lack of objective evidence in the specification and the teachings of the prior art which counter-indicate the administration of a TNF homolog for the treatment of cardiovascular disease, one of skill in the art would be subject to undue experimentation without reasonable expectation of success n order to practice the claimed invention

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 4-6 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al (US 5,998,171, reference of the IDS filed Feb 14, 2001).

The specific embodiments of the claims are recited above. Yu et al disclose a method of treating tumor comprising the administration of endokine alpha through a local injection of endokine alpha or isolated limb perfusion of endokine alpha (column 28, lines 26-30). Endokine alpha consists of residues 9-177 of the instant SEQ ID NO:14. The specification states (page 23, lines 1-2) that a preferred embodiment is a polypeptide comprising residues 52-177 of SEQ ID NO:14. Yu et al also disclose a method of treating tumors comprising conjugating endokine alpha with cytostatic drugs (column 28, lines 23-26), thus fulfilling the specific embodiment of claim 12 drawn to the administration of the PRO175 polypeptide in combination with a growth inhibitory agent.

Claims 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al (US 200200146389, priority to 60/065635 and 60/069661).

The specific embodiments of the claims are recited above. Ashkenazi et al disclose a method for treating cancer comprising the administration of the DNA19355 polypeptide which is identical to the instant SEQ ID NO:14 (paragraphs [0120] to [0129]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al (US 200200146389) in view of Yu et al (US 5,998,171).

Ashkenazi et al teach a method for treating cancer comprising the administration of the instant SEQ ID NO:14 as a DNA19355 polypeptide. Ashkenazi et al teach that said polypeptide is a homologue to TNF alpha (title). Ashkenazi et al teach that said method can be combined with the administration of other apoptosis inducing agents and chemotherapeutic drugs (paragraphs [0121] and [0126]). Ashkenazi et al do not specifically teach the conjugation of SEQ ID NO:14 with said drugs and agents.

Yu et al teach a method of treating tumors comprising conjugating endokine alpha with cytostatic drugs (column 28, lines 23-26). Yu et al teach that endokine alpha is a homologue of TNF alpha (column 3, lines 58-63).

It would have been prima facie obvious at the time the invention was made to treat cancer in a mammal by the administration of a DNA19355 polypeptide conjugated to a cytostatic drug . One of skill in the art would have been motivated to do so by the teachings of Yu et al on the administration of endokine alpha conjugated to a cytostatic drug. One of skill in the art would conclude that because bought endokine alpha and the DNA19355 polypeptide are taught to by TNF-alpha homologues and taught to be effective targeting and killing cancer cells, that the anti-cancer properties of the DNA19355 polypeptide conjugated to a cytostatic drug would be the same as the anti-cancer properties of the endokine alpha conjugated to a cytotstatic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
Art Unit 1642

Karen A. Canella
KAREN A. CANELLA PH.D
PRIMARY EXAMINER